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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,976	01/07/2004	Siau-Way Liew	3155/121	6434

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EXAMINER	
RAMIREZ, JOHN FERNANDO	
ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,976	LIEW ET AL.	
	Examiner	Art Unit	
	John F. Ramirez	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

After a review of applicant's remarks, all necessary changes to the claims have been entered. Accordingly, claims 20 and 21 have been entered.

Applicant's arguments filed September 11, 2006 with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection. Therefore, the following office action is provided in order to expedite the prosecution of this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 7, 9-11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wherli et al. (US 5,247,934).

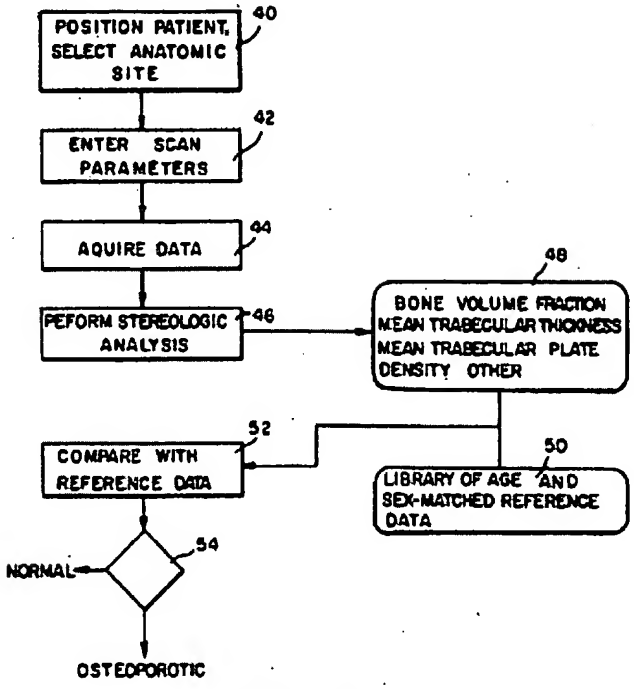

FIG. 4

A method of predicting bone or articular disease in a subject, the method comprising the steps of: determining one or more micro-structural parameters, one or more macroanatomical parameters or biomechanical parameters of a joint in said subject, wherein determining includes extracting trabecular micro-structure from an image of said subject; and combining at least two said parameters to predict the risk of bone or articular disease, the at least two said parameters including two or more of a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter, wherein said combining comprises combining one or more micro-structural parameters and one or more macro-anatomical parameters, wherein said bone or articular disease is fracture risk, wherein the parameters are obtained from one or more regions of interest in an image obtained from said subject, wherein said parameters are selected from the group consisting of one or more micro-structural parameters, one or

more macroanatomical parameters or biomechanical parameters, wherein said combining comprises univariate, bivariate or multivariate statistical analysis, and further comprising comparing said parameters to data derived from a reference database of known disease parameters (see Abstract, figure 4 and related description, col. 4, lines 32-64; col. 8, lines 10-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5, 8, 12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wherli et al. (US 5,247,934) in view of Mazess (US 5,673,298) in further view of Arnold (US 5,335,260) and in further view of Paul et al. (US 5,320,102).

The Wherli et al. patent teaches all the limitations of the claimed subject matter except for mentioning specifically the steps of: wherein said combining comprises combining one or more micro-structural parameters and one or more biomechanical parameters, wherein said combining comprises combining one or more macroanatomical parameters and one or more biomechanical parameters, wherein said combining comprises combining one or more macroanatomical parameters, one or more micro-structural parameters and one or more biomechanical parameters, wherein the image comprises a calibration phantom, wherein the bone is in a region selected

from the group consisting of leg, knee, hip, spine and arm, wherein said parameters are selected from the group consisting of total cartilage volume; focal cartilage volume; a cartilage thickness distribution or thickness map; mean cartilage thickness over substantially total surface and etc. as claimed in claim 20, and wherein said parameters are selected from the group consisting of: a presence or absence of bone marrow edema; a volume of bone marrow edema and etc. as claimed in claim 21.

However, the steps of wherein said combining comprises combining one or more micro-structural parameters and one or more biomechanical parameters, wherein said combining comprises combining one or more macroanatomical parameters and one or more biomechanical parameters; wherein said combining comprises combining one or more macroanatomical parameters, one or more micro-structural parameters and one or more biomechanical parameters, wherein the image comprises a calibration phantom, wherein the bone is in a region selected from the group consisting of leg, knee, hip, spine and arm, wherein said parameters are selected from the group consisting of total cartilage volume; focal cartilage volume; a cartilage thickness distribution or thickness map; mean cartilage thickness over substantially total surface and other parameters as claimed in claim 20, and wherein said parameters are selected from the group consisting of: a presence or absence of bone marrow edema; a volume of bone marrow edema and other parameters as claimed in claim 21 are considered conventional in the art as evidenced by the teachings of Mazess (US 5,673,298), Arnold (US 5,335,260) and Paul et al. (US 5,320,102).

The Mazess patent teaches the steps of wherein said combining comprises combining one or more micro-structural parameters and one or more biomechanical parameters, wherein said combining comprises combining one or more macroanatomical parameters and one or more biomechanical parameters, wherein said combining comprises combining one or more macroanatomical parameters, one or more micro-structural parameters and one or more biomechanical parameters (see abstract, figures 13-15 and related description). Moreover, the Arnold patent teaches the step wherein the image comprises a calibration phantom (see abstract), and furthermore, the Paul et al. patent teaches the steps of wherein the bone is in a region selected from the group consisting of leg, knee, hip, spine and arm, wherein said parameters are selected from the group consisting of total cartilage volume; focal cartilage volume; a cartilage thickness distribution or thickness map; mean cartilage thickness over substantially total surface and other parameters as claimed in claim 20, and wherein said parameters are selected from the group consisting of: a presence or absence of bone marrow edema; a volume of bone marrow edema and other parameters as claimed in claim 21 (see abstract, col. 2, lines 40-68, see figures 4a-4c and related description).

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Wherli, with the above discussed enhancements would provide a better non-invasive method employing quantitative techniques for analyzing and diagnosing diseases that affect patient's bones.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wherli et al. (US 5,247,934) in view of Pak et al. (US 5,228,445).

In reference to claims 14-19, the Pak et al. patent teaches all the limitations of the claimed subject matter except for mentioning specifically the steps of administering a compound to the subject, wherein determining and combining are repeated at two or more time points and further wherein one time point is prior to administration of the compound, a method of determining the effect of a candidate agent on a subject's prognosis for musculoskeletal disease comprising: predicting a first risk of musculoskeletal disease in subject administering a candidate agent to said subject; predicting a second risk of said musculoskeletal disease in said subject and comparing said first and second risks, thereby determining the effect of the candidate on the subject's prognosis for said disease, wherein said candidate agent is administered to the subject, wherein said administration comprises ingestion or injection, wherein said candidate agent is selected from the group consisting of molecules, pharmaceuticals, biopharmaceuticals, agropharmaceuticals and combinations thereof.

However, the steps of 1) administering a compound to the subject, 2) wherein determining and combining are repeated at two or more time points and further wherein one time point is prior to administration of the compound, 3) a method of determining the effect of a candidate agent on a subject's prognosis for musculoskeletal disease comprising: predicting a first risk of musculoskeletal disease in subject, 4) administering a candidate agent to said subject, 5) predicting a second risk of said musculoskeletal disease in said subject, 6) comparing said first and second risks, thereby determining

the effect of the candidate on the subject's prognosis for said disease, 7) wherein said candidate agent is administered to the subject, 8) wherein said administration comprises ingestion or injection, and 9) wherein said candidate agent is selected from the group consisting of molecules, pharmaceuticals, biopharmaceuticals, agropharmaceuticals and combinations thereof are considered conventional in the art as evidenced by the teachings of Pak et al. (see abstract, col. 15, line 49 – col. 16, line 19; col. 19, lines 31-54; .

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Wherli, with the above discussed enhancements would provide a better non-invasive method employing quantitative techniques for analyzing and diagnosing diseases that affect patient's bones.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:30 - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JFR
11/29/06

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